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Biotechnology

Agricultural Biotechnology Report

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Report Highlights:
This report updates CA5044. 2005 data on crop average sown and crop size dedicated to genetically modified varieties was largely unavailable. Areas of this report that have been updated include data on crops submitted for regulatory approval, field trials submissions, and approved biotech crops.

Includes PSD Changes: No
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SECTION I. EXECUTIVE SUMMARY

The United States is Canada's most important and largest trading partner, with Canada exporting roughly 60% of its agricultural products to the United States on an annual basis. In addition, Canada is the number one export market for U.S. agriculture products. The U.S. exports roughly 16% of its agriculture products to Canada on annual basis. The signing of the Free Trade Agreement and the North American Free Trade Agreement has greatly increased the flow of products in both directions. In addition, Canada, the U.S. and Mexico are working cooperatively in the development of regulatory policy related to the biotechnology sectors in the three countries, through the North American Biotechnology Initiative (NABI).

Canada is a signatory to the Cartagena Protocol, but there has been no movement by the Government of Canada to ratify it. Within the Canadian agriculture industry there has been strong arguments for and strong arguments against the Protocol's ratification. As of this date, the Government of Canada is continuing to consult with members of the industry to determine the best course of action for Canadian agriculture. Canada relies heavily on U.S. exports of major grains and oilseeds like corn and soybeans to meet the needs of its processing and livestock industries. The ratification of the Protocol by Canada could have an impact on future imports of genetically modified grains from the United States.

Canada's regulatory system is science-based. Canada is the only country in world whose regulatory process is based upon the traits expressed and not on the basis of the method used to introduce the traits. This is why in Canada biotechnology is defined as "the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms." This broad definition encompasses products produced through various techniques including conventional breeding, mutagenesis, and genetic engineering.

In order to obtain regulatory approval for a plant with novel traits (PNTs) or novel foods, the products must go through the six-steps of Canada's regulatory process. The Canadian Food Inspection Agency (CFIA), Health Canada and Environment Canada are the primary agencies responsible for monitoring and regulating the approval of a new product. The CFIA is responsible for granting approval for commercial release and use of a new product in livestock feed. Health Canada is responsible for providing approval for the consumption of a new product in the human food market. Environment Canada is involved when there is potential impact on the environment by a new product. From the time of development to the approval of a PNT or novel food can take anywhere between seven to ten years, and in some instances even longer.

There has been a push by some industry groups to modify Canada's regulatory approval process to include a market approval component (cost-benefit analysis) as a condition for regulatory approval. This proposed change to the regulatory system has met significant opposition from other industry groups, who have indicated that the regulatory system should remain science-based, with market considerations being done in addition to, but not as a requirement for regulatory approval.

Canada's biotech industry continues to grow as more and more producers are relying on biotech crops to meet their needs. According to "The Global Diffusion of Plant Biotechnology: International Adoption and Research in 2004," Canada has researched more field crops than any other country. With institutions like Agriculture and Agri-Food Canada, Genome Canada, Plant Biotechnology Institute, the University of Guelph, the University of Saskatchewan, Laval University and all private companies investing time and money into the development of new crops in Canada, the biotech industry in the country will continue to flourish and grow.

SECTION II. BIOTECHNOLOGY TRADE AND PRODUCTION

2005 production and trade data was largely unavailable. In 2004, Canada was the third largest producer of biotech crops in the world, with 5.4 million hectares planted, following behind the United States and Argentina respectively. The three major biotech crops produced in Canada are corn, canola and soybeans, which are all genetically modified (GM). The three crops' combined area grew 23% in 2004, with 77% of the canola acreage planted to GM varieties. In Western Canada, the primary canola growing region in Canada, over 90% of the acres were sown to herbicide tolerant canola. With the continual development of new GM varieties, the expectation is that the area sown to GM crops in

Canada will continue to increase. This is especially true with the development of GM crops that are considered a health benefit. For example, some varieties of canola and soybeans have been developed with modified fatty acid contents to cater to the populace concerned about trans fatty acids. In addition, the acreage planted to spring wheat developed through mutagenesis is increasing in Canada and this trend is expected to continue as varieties of wheat resistant to fusarium are developed. Monsanto had applied for regulatory approval for Roundup Ready wheat, but has since withdrawn plans to introduce the crop on the market as a result of strong opposition from groups like the Canadian Wheat Board (CWB) and the National Farmers Union (NFU).

Ontario and Quebec are the primary corn and soybean producing provinces in Canada. In Ontario, preliminary figures for 2005 suggest that 40% of corn and 43% of soybean acreages are planted with GM crops. In 2004, approximately 90% of the canola acreage in Ontario was GM (no 2005 data available). In 2005, corn and soybean acreage in Ontario is projected at 650 thousand hectares and 925 thousand hectares, respectively. The proportion of acreage planted to GM corn and soybean has been increasing and expected to continue to increase. In Quebec, approximately 51% of corn acreage and 42% of soybean acreage are dedicated to GM crops.

The Canadian Food Inspection Agency (CFIA) is one of the regulatory bodies responsible for determining whether plants with novel traits (PNTs) are safe for use in feed and release into the environment. The regulatory approval procedure is ongoing and the CFIA is continually receiving new PNTs to assess. Below is a list of PNTs that have been submitted to the CFIA as of August 2006 in attempt to get regulatory approval.

Table 1. Crops Submitted for Regulatory Approval

Product for Submission	Developer
Corn (Event LY038), genetically modified for elevated levels of free lysine in grain	Monsanto Canada, Inc.
Corn (MON 99017), genetically modified for insect resistance and glyphosate herbicide tolerance	Monsanto Canada, Inc.
Corn (TC6275), genetically modified for insect resistance	DOW AgroSciences Canada, Inc.
Cotton (MON 88913), genetically modified for glyphosate herbicide tolerance	Monsanto Canada, Inc.
Durum Wheat (ALS2), genetically modified for herbicide tolernace	BASF
Durum Wheat (ALS3)B, genetically modified for herbicide tolernace	BASF
Wheat (ALS3), bred for herbicide tolerance	BASF
Wheat (ALS1b), genetically modified for herbicide tolerance	BASF

Source: Canadian Food Inspection Agency

The time between when a PNT is granted regulatory approval by the CFIA and Health Canada for commercial release and the when a PNT is introduced into the market is dependent upon the company producing the product.

Imports

Canada imports biotechnology crops and products. This includes grains and oilseeds, specifically corn and soybeans. Many of Canada's secondary industries like the ethanol industry in Ontario rely on the large supply of U.S. corn that is available right across the border. In addition, Canada's hog industry and to a lesser extent the beef industry also rely on corn and soybean imports from the United States. As a majority of the corn and soybeans grown in U.S. are GM, this is what Canada imports. In addition, Canada also imports GM papaya from Hawaii.

Development of Biotech Crops

A majority of the biotech products that have received regulatory approval in Canada have also gone through the regulatory process in the United States. It is an unwritten rule, but a general understanding that when a company chooses to introduce a new biotech product, regulatory approval is sought in both Canada and the United States. Because of the quantity and free flow of goods moving across the border on a daily basis, many of the multinationals, which generally have offices on both sides of the border, apply for regulatory approval for a PNT in both the U.S. and Canada at or close to the same time. This ensures than anything that is approved in one country is not hindered in its movement to the other country by lack of regulatory approval. In addition, approval in both countries eliminates any issues that may arise due to accidental contamination. There are many instances were GM crops not grown in Canada have obtained regulatory approval here because those crops are grown in the United States. For example, the Canadian climate does permit the growing of cotton, but several varieties of GM cotton have been approved in Canada. For the most part, biotech products that have received regulatory approval in Canada will most likely apply for regulatory approval in the United States. For products like wheat and canola developed through mutagenesis, which by the definition of biotechnology in Canada fall under the PNT heading and require regulatory approval, do not require regulatory approval in the United States.

SECTION III. BIOTECHNOLOGY POLICY

Canada's Regulatory System

Canada has an extensive science-based regulatory framework used in the approval process of agricultural products produced through biotechnology. Plants or products that are created with different or new traits from their conventional counterparts are referred to in the Canadian regulatory guidelines and legislation as plants with novel traits (PNTs) or novel foods. Plants with novel traits are defined as:

- A plant variety/genotype possessing characteristics that demonstrate neither familiarity nor substantial equivalence to those present in a distinct, stable population of a cultivated seed in Canada and that have been intentionally selected, created or introduced into a population of that species through a specific genetic change. Plants included under this definition are plants that are produced using recombinant DNA (rDNA) techniques, chemical mutagenesis, cell fusion and conventional cross breeding.

A novel food is defined as:

1. A substance, including a microorganism that does not have a history of safe use as a food.

2. A food that has been manufactured, prepared, preserved or packaged by a process that has not been previously applied to that food, and causes the food to undergo a major change.

3. A food that is derived from a plant, animal or microorganism that has been genetically modified such that the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism; the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism; or one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

The Canadian Food Inspection Agency (CFIA), Health Canada (HC) and Environment Canada (EC) are the three agencies are responsible for the regulation and approval of products derived from biotechnology. The three agencies work together to monitor development of plants with novel traits, novel foods and all plants or products with new characteristics not previously used in agriculture and food production.

The CFIA is responsible for regulating the importation, environmental release, variety registration, and the use in livestock feeds of PNTs. Health Canada is responsible for assessing the human health safety of foods, including novel foods, and approving their use in commerce. Environment Canada is responsible for administering the New Substances Notification Regulations and for performing environmental risk assessments of *Canadian Environmental Protection Act* (CEPA) toxic substance, including organisms and microorganisms that may have been derived through biotechnology.

Table 2. Regulating Agencies and Relevant Legislation

Department/Agency	Products Regulated	Relevant Legislation	Regulations
Canadian Food Inspection Agency	Plants and seeds, including those with novel traits, Animals, Animals vaccines and biologics, Fertilizers, Livestock feeds	*Consumer Packaging and Labeling Act,* *Feeds Act,* *Fertilizer Act,* *Food and Drugs Act,* *Health of Animals Act,* *Seeds Act,* *Plant Protection Act*	*Feeds Regulations,* *Fertilizer Regulations,* *Health of Animals Regulations,* *Food and Drug Regulations*
Environment Canada	Biotechnology products under CEPA, such as microorganisms used in bioremediation, Waste disposal, mineral leaching or enhanced oil recovery	*Canadian Environmental Protection Act* (CEPA)	*New Substances Notification Regulations* (These regulations apply to products not regulated under other federal legislation)
Health Canada	Foods, Drugs, Cosmetics, Medical devices, Pest control products	*Food and Drugs Act,* *Canadian Environmental Protection Act,* *Pest Control Products Act*	*Cosmetics Regulations,* *Food and Drug Regulations,* *Novel Foods Regulations,* *Medical Devices Regulations,* *New Substances Notification Regulations,* *Pest Control Products Regulation*
Fisheries and Oceans	Potential environmental release of transgenic aquatic organisms	*Fisheries Act*	Under development

Table 3. Agencies' Responsibilities

Category	CFIA	Health Canada	Environment Canada
Human Health & Food Safety			
• Approval of novel foods		X	
• Allergens		X	
• Nutritional content		X	
• Potential presence of toxins		X	
Food Labeling Policies			
• Nutritional content		X	
• Allergens		X	
• Special dietary needs		X	
• Fraud and consumer protection	X		
Safety Assessments			
• Fertilizers	X		
• Seeds	X		
• Plants	X		

• Animals • Animal vaccines • Animal feeds	X X X		
Testing Standards • Guidelines for Testing Effects on Environment			X

Plants with novels traits are subjected to examination under Canada's six-step regulatory process. The six steps are:

1. Scientists working with genetically modified organisms, including the development of PNTs, adhere to Canadian Institute for Health Research directives, as well as the codes of practice of their own institutional biosafety committees. These guidelines protect the health and safety of laboratory staff and ensure environmental containment.

2. The CFIA monitors all PNT field trials to comply with guidelines for environmental safety and to ensure confinement, so that the transfer of pollen to neighboring fields does not occur.

3. The CFIA scrutinizes the transportation of seed to and from trial sites as well as the movement of all harvested plant material. The CFIA also strictly controls the importation of all seeds, living plants and plant parts, which includes plants containing novel traits.

In 2005, Canada had 90 submissions and 208 field trials of various crops from numerous companies.

Table 4. Field Trials in 2005

Crop	Field Trials	Herbicide Tolerance	Stress Tolerance	Genetic Research	Modified Oil	Male Sterility/ Restoration	Insect Resistance	Enhanced Yield	Other	Province of field Trial
Alfalfa	4								4	SK
Brown Mustard	12	12				4				SK
Canola/ napus	121	30	7	4	12	13	3	68	18	SK, AB, MB, ON
Corn	26	13	4		4		13			ON
Creeping Bentgrass	3	3								ON
Durum Wheat	2	2								SK
Potato	8		7						1	SK, MN
Safflower	9	9							9	AB
Soybean	6	6			3					ON
Sugar Beet	2	2								AB, SK
Tobacco	1								1	ON
Trees	2						1			QC
Wheat	11	2							9	MB, ON, AB

Source: Canadian Food Inspection Agency
Note: Some field trials had more than one breeding objective; therefore in some instances the number of field trials listed may exceed the total number of trials authorized. In addition, some field trials do not take place once authorized.
(Provinces: AB-Alberta, MB-Manitoba, ON-Ontario, QC-Quebec, SK-Saskatchewan)

4. Before any PNT is permitted to be grown outside of confined trials, CFIA must complete an environmental safety assessment focusing on:
    - Potential for movement of the novel trait to related plant species
    - Impact on non-target organisms (including insects, birds and mammals)
    - Impact on biodiversity
    - Potential for weed infestations arising from the introduced trait(s)
    - Potential for the novel plant to become a plant pest

    ❑ The CFIA evaluates all livestock feeds for safety and efficacy, including nutritional value, toxicity and stability. Data submitted for novel feeds include a description of the organism and genetic modification, intended use, environmental fate and potential for the gene (or metabolic) products to reach the human food chain. Safety aspects cover the animal eating the feed, consumption of the animal product by humans, worker safety and any environmental impacts related to use of the feed.

    ❑ Health Canada is responsible for assessing food with no previous history of safe use or food that is manufactured by a new process that causes a significant change in composition or is derived from an organism genetically modified to possess novel trait(s). Health Canada developed the *Guidelines for the Safety Assessment of Novel Foods, Volumes I and II*, in consultation with experts from the international community, including the Food and Agriculture Organization (FAO), the World Health Organization (WHO) and the Organization for Economic Co-operation and Development (OECD). Using the *Guidelines for the Safety Assessment of Novel Foods*, Health Canada examines:

    - How the food crop was developed, including molecular biological data
    - Composition of the novel food, compared to non-modified counterparts
    - Nutritional data for the novel food, compared to non-modified counterparts
    - Potential for new toxins
    - Potential for causing any allergic reaction
    - Dietary exposure by the average consumer and population sub-groups (such as children)

5. Canada's system of registration for newly developed crop varieties ensures that only varieties with proven benefits to producers and consumers are sold. Once approved for use in field trials, varieties are evaluated in regional field trials. Plant varieties produced through biotechnology cannot be registered and sold in Canada until authorized for environmental, livestock feed and food safety.

    Developers of plants with stacked traits, which were created from previously authorized PNTs, are required to notify the CFIA's Plant Biosafety Office (PBO) at least 60 days prior to the anticipated date of the environmental release of these plants. Following notification, the PBO may issue a letter (within 60 days of notification) informing the developer of any concerns it may have regarding the proposed unconfined environmental release. The PBO may also request and review data to support the safe use of the modified plant in the environment. Stacking of traits with potential incompatible management requirements, possible negative synergistic effects, or where production of the plant may be extended to a new area of the country, may require an environmental safety assessment. Until all environmental safety concerns have been resolved, the modified plant should not be released in the environment.

6. Once environmental, feed and food safety authorizations are granted, the PNT and feed and food products derived from it can enter the marketplace, but are still subject to the same regulatory scrutiny that applies to all conventional products in Canada. In addition, any new information arising about the safety of a PNT or its food products must be reported to government regulators who, upon further investigation, may amend or revoke authorization and/or immediately remove the product(s) from the marketplace.

From development to the time the product has been approved for human consumption can take anywhere between seven to ten years. In some instances the process takes longer than 10 years.

In order to maintain the integrity of Canada's regulatory system, several advisory committees have been established to monitor and advise the government of current and future regulatory needs. The Canadian Biotechnology Advisory Committee (CBAC) was established in 1999 to advise the government on ethical, social, scientific, economic, regulatory, environmental and health aspects. The CBAC released a report *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada* in August 2001. Scientists from the Royal Society of Canada have also prepared a report to help strengthen Canada's regulatory system for future crops.

There has been a concentrated push from various farm groups within Canada's agriculture industry, like the Canadian Wheat Board, the Canadian Federation of Agriculture and others, to modify Canada's regulatory system to include a cost-benefit analysis as a part of the regulatory process prior to the release of a novel plant, with specific focus on those crops produced through genetic modification. These groups are not proposing that this change be applied to all novel food and PNTs, but more specifically be applied only to field crops. In addition, these groups also propose that a cost-benefit analysis to certain crops only be applied to certain crops. The argument put forth by the groups striving for this change is that the current regulatory system allows for the introduction of a new product created through biotechnology, without taking into consideration what the impact the product may have on the marketplace. These groups want to ensure that potential market impact, system compatibility, economic benefits and costs to farmers are considered and adequately addressed prior to the unconfined release and production of new agricultural products in Canada. Farm groups like the Grain Growers of Canada, Agricore United and many others strongly oppose amending Canada's regulatory framework and adding a cost-benefit analysis as a requirement for the approval of any plant or foods with novel traits. These groups believe that Canada has one of the best regulatory processes in the world and it should remain science-driven, with the decision for or against approval be science-based, not market-based. These groups forecast that adding a cost-benefit analysis to the regulatory approval process will only bog it down, and add unnecessary additional layers to the already complex and intricate approval process. The addition of a cost-benefit analysis could further delay the introduction of crops that could be beneficial to Canadian producers, putting them at a competitive disadvantage with competing countries, who have already approved the product, including the United States. During the debate regarding the approval of Round-up Ready wheat, the groups that opposed the changes to the regulatory process conceded to include a market impact study done in addition to the regulatory approval, but approval of the product was not contingent on findings of the market impact study.

Table 5. Approved Biotech Crops in Canada

Crop	Trait Category	Applicant(s)	Event(s)	Trait Description(s)	Reviewed Uses within Canada
Alfalfa	Herbicide Tolerance	Monsanto Company and Forage Genetics International	J101, J163	Glyphosate herbicide tolerant alfalfa (lucerne) produced by inserting a gene encoding the enzyme 5-enolypyruvylshikimate-3-phosphate synthase (EPSPS) from the CP4 strain of *Agrobacterium tumefaciens*.	Feed
Canola/Brassica napus	Herbicide Tolerance	Bayer CropScience (Aventis CropScience (AgrEvo Canada))	HCN92	Glufosinate ammonium tolerant; Phosphinothricin acetyltransferase (PAT) from *Streptomyces viridochromogenes*	Environment, food, and feed

Canola/Brassica napus	Herbicide Tolerance	Monsanto Canada	GT73,RT73	Glyphosate tolerant; Enzymes 5-enolypyruvylshikimate-3-phosphate synthase (EPSPS) from the CP4 strain of *Agrobacterium tumefaciens* and glyphosate oxidase from *Ochrobactrum anthropi*	Environment, food, and feed
Canola/Brassica napus	Herbicide Tolerance	Pioneer Hi-Bred InternationalInc.	NS738, NS1471, NS1473	Imidazolinone tolerant; Selection of somaclonal variants with altered acetolactate synthase (ALS) enzymes, following chemical mutagenesis	Environment, food, and feed
Canola/Brassica napus	Modified seed fatty acid content	Calgene (currently Monsanto)	23-198, 23-18-17	Higher laurate and myristate content, thioesterase encoding gene from the California bay laurel (*Umbellularia californica)*	Environment, food, and feed
Canola/Brassica napus	Herbicide Tolerance	Monsanto Canada	GT200	Glyphosate tolerant; enzymes 5-enolypyruvylshikimate-3-phosphate synthase (EPSPS) from the CP4 strain of *Agrobacterium tumefaciens* and glyphosate oxidase from *Ochrobactrum anthropi*	Environment, food, and feed
Canola/Brassica napus	Herbicide Tolerance	Bayer CropScience (Aventis CropScience (AgrEvo Canada))	T45(HCN28)	Glufosinate ammonium tolerant; phosphinothricin-N-acetyltransferase (PAT) isolated from the common aerobic soil actinomycete, *Streptomyces viridochromogenes*	Environment, food, and feed
Canola/Brassica napus	Modified seed fatty acid content	Pioneer Hi-Bred International Inc.	45A37, 46A40	High oleic acid and low linolenic acid content; chemical mutagenesis through exposure to a solution of ethylnitrosourea (8 mM) in dimethylsulfoxide	Food
Canola/Brassica napus	Modified seed fatty acid content	Pioneer Hi-Bred International Inc.	46A12, 46A16	High oleic acid and low linolenic acid content; chemical mutagenesis through exposure to a solution of ethylnitrosourea (8 mM) in dimethylsulfoxide	Food
Canola/Brassica napus	Herbicide Tolerance	Bayer CropScience (Aventis CropScience)	HCN10	Glufosinate ammonium tolerant; Phosphinothricin acetyltransferase (PAT) from *Streptomyces viridochromogenes*	Environment, food, and feed

Canola/Brassica napus	Male-sterility/ fertility restoration, herbicide tolerance	Bayer CropScience (Plant Genetic Systems)	MS1, RF1 => PGS1	Glufosinate ammonium herbicide tolerance and fertility restored; MS lines contained the *barnase* gene from *Bacillus amyloliquefaciens*, RF lines contained the *barstar* gene from the same bacteria, and both lines contained the phosphinothricin N-acetyltransferase (PAT) encoding gene from *Streptomyces hygroscopicus*.	Environment, food, and feed
Canola/Brassica napus	Male-sterility/ fertility restoration, herbicide tolerance	Bayer CropScience (Plant Genetic Systems)	MS1, RF2 =>PGS2	Glufosinate ammonium herbicide tolerance and fertility restored; MS lines contained the *barnase* gene from *Bacillus amyloliquefaciens*, RF lines contained the *barstar* gene from the same bacteria, and both lines contained the phosphinothricin N-acetyltransferase (PAT) encoding gene from *Streptomyces hygroscopicus*.	Environment, food, and feed
Canola/Brassica napus	Male-sterility/ fertility restoration, herbicide tolerance	Bayer CropSceince (Plant Genetic Systems)	MS8xRF3	Glufosinate ammonium herbicide tolerance and fertility restored; MS lines contained the *barnase* gene from *Bacillus amyloliquefaciens*, RF lines contained the *barstar* gene from the same bacteria, and both lines contained the phosphinothricin N-acetyltransferase (PAT) encoding gene from *Streptomyces hygroscopicus*.	Environment, food, and feed
Canola/Brassica napus	Herbicide Tolerance	Bayer CropScience (Rhone Poulenc Inc.)	OXY-235	Oxynil (bromoxynil and ioxynil) tolerant; nitrilase gene from Klebsiella pneumoniae	Environment, food, and feed
Canola/Brassica rapa	Herbicide Tolerance	Monsanto Canada	ZSR500/502	Glyphosate tolerant; Inter-specific cross with transgenic Brassica napus canola line GT73.	Environment and feed. Not considered novel for food.
Canola/Brassica rapa	Herbicide Tolerance	Bayer CropScience (Aventis CropScience (AgrEvo Canada))	HCR-1	Glufosinate ammonium herbicide tolerance; Inter-specific cross with transgenic*Brassica napus* canola line T45	Environment and feed. Not considered novel for food.
Corn / Zea mays	Insect Resistance, Herbicide Tolerance	Syngenta Seeds, Inc.	176	European Corn Borer resistant, Glufosinate ammonium herbicide tolerant; *Cry1Ab* from *Bacillus thuringiensis* (Bt)	Environment, food, and feed

Corn / Zea mays	Herbicide Tolerance	Pioneer Hi-Bred International Inc.	3751IR	Imidazolinone herbicide tolerant; developed from a mutant line (XA17) selected from somatic (non-reproductive) maize embryos grown on imidazolinone-enriched media under conditions designed to induce mutation.	Environment, food, and feed
Corn / Zea mays	Herbicide Tolerance	Syngenta Seeds, Inc.	EXP1910IT	Imidazolinone herbicide tolerance, specifically imazethapyr; Chemically induced pollen mutagenesis	Environment, food, and feed
Corn / Zea mays	Insect Resistance, Herbicide Tolerance	Syngenta Seeds, Inc.	Bt11 (X4334CBR, X4737CBR)	European Corn Borer resistant, Glufosinate ammonium herbicide tolerant; *cry1Ab* from *Bacillus thuringiensis* and *pat* from *Streptomyces viridochromogenes*	Environment, food, and feed
Corn / Zea mays	Herbicide Tolerance	BASF Inc.	DK404SR	Sethoxydim tolerant; Selection of somaclonal variants from embryo cultures	Environment, food, and feed
Corn / Zea mays	Herbicide Tolerance	Bayer CropScience (Aventis CropScience (AgrEvo Canada))	T14, T25	Glufosinate ammonium tolerant; phosphinothricin-N-acetyltransferase (PAT) from *Streptomyces viridochromogenes*	Environment, food, and feed
Corn / Zea mays	Herbicide Tolerance	Monsanto Canada (Dekalb Genetics Corporation)	B16(DLL25)	Glufosinate ammonium tolerant; phosphinothricin-N-acetyltransferase (PAT) from *Streptomyces viridochromogenes*	Environment, food, and feed
Corn / Zea mays	Herbicide Tolerance, male sterility	Bayer CropScience (Aventis CropScience (AgrEvo Canada))	MS3	Glufosinate ammonium tolerant and male sterility; phosphinothricin-N-acetyltransferase (PAT) from *Streptomyces viridochromogenes,* barnase gene, isolated from *Bacillus amyloliquefaciens*	Environment, food, and feed
Corn / Zea mays	Insect Resistance, Herbicide Tolerance	Pioneer Hi-Bred International Inc.	MON809	European Corn Borer Resistant, Glyphosate Tolerant, *cry1Ab* from *Bacillus thuringiensis* (*Bt*)	Environment, food, and feed
Corn / Zea mays	Insect Resistance	Monsanto Canada	MON810	European Corn Borer Resistant; *cry1Ab* from *Bacillus thuringiensis* (*Bt*)	Environment, food, and feed
Corn / Zea mays	Insect Resistance, Herbicide Tolerance	Monsanto Canada (Dekalb Genetics Corporation)	DBT418	European Corn Borer resistant, Glufosinate ammonium herbicide tolerant; *cry1Ac* from *Bacillus thuringiensis* (*Bt*) and *bar* (phosphinothricin N-acetyltransferase (PAT)) from *Streptomyces hygroscopicus*	Environment, food, and feed

Corn / Zea mays	Insect Resistance, Herbicide Tolerance	Monsanto Canada	MON802	European Corn Borer Resistant, Glyphosate Tolerant; *cry1Ab* gene, isolated from the common soil bacterium *Bacillus thuringiensis* (*Bt*), CP4 EPSPS from *Agrobacterium tumefaciens* and *goxv247* from *Ochrobactrum anthropi* strain LBAA	Environment, food, and feed
Corn / Zea mays	Herbicide Tolerance	Monsanto Canada	MON832	Glyphosate Tolerant; EPSPS from strain CP4 of *Agrobacterium tumefaciens* and *goxv*247 from strain LBAA of *Ochrobactrum anthropi*	Food
Corn / Zea mays	Herbicide Tolerance	Monsanto Canada	GA21	Glyphosate Tolerant; particle acceleration (biolistic) transformation	Environment, food, and feed
Corn / Zea mays	Herbicide Tolerance	Monsanto Canada	NK603	Glyphosate Tolerant; EPSPS from the CP4 strain of *Agrobacterium tumefaciens*	Environment, food, and feed
Corn / Zea mays	Insect Resistance, Herbicide Tolerance	Mycogen (c/o Dow AgroSciences); Pioneer Hi-Bred International Inc.	TC1507	European Corn Borer resistant, Glufosinate ammonium herbicide tolerant; *cry1Fa2* from *Bacillus thuringiensis* (*Bt*) var. *aizawai* and phosphinothricin-N-acetyltransferase (PAT) from *Streptomyces viridochromogenes*	Environment, food, and feed
Corn / Zea mays	Pest Resistance	Monsanto Canada	MON863	Western and Northern Corn Rootworm Resistant; *cry3Bb1* from *Bacillus thuringiensis* (subsp. kumamotoensis)	Environment, food, and feed
Corn / Zea mays	Herbicide Tolerance	Pioneer Hi-Bred International Inc.	IT	Imidazolinone herbicide tolerance; *In vitro* selection, mutation XI-12	Food
Corn / Zea mays	Herbicide Tolerance/ Pest Resistance	Monsanto Company	MON88017	Corn rootworm-resistant maize produced by inserting the cry3Bb1 gene from Bacillus thuringiensis subspecies kumamotoensis strain EG4691. Glyphosate tolerance derived by inserting a 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) encoding gene from Agrobacterium tumefaciens strain CP4.	Food and feed
Cotton Seed / Gossypium hirsutum L.	Pest Resistance	Monsanto Canada	MON531/757/ 1076	Lepidopteran Resistant including, but not limited to, cotton bollworm, pink bollworm, tobacco budworm; *cry1Ac* from *Bacillus thuringiensis* (*Bt*),	Food and feed. Not grown in Canada

Cotton Seed / Gossypium hirsutum L.	Herbicide Tolerance	Monsanto Canada	MON1445/1698	Glyphosate Tolerant; -enolpyruvylshikimate-3-phosphate synthase (EPSPS) from CP4 strain of *Agrobacterium tumefaciens*	Feed (both lines) and food (1445 only). Not grown in Canada
Cotton Seed / Gossypium hirsutum L.	Herbicide Tolerance	Monsanto Canada (Calgene Inc.)	BXN lines	Oxynil (Bromoxynil and Ioxynil) Tolerant; *bxn* from *Klebsiella pneumoniae*	Food and feed. Not grown in Canada
Cotton Seed / Gossypium hirsutum L.	Pest Resistance	Monsanto Canada	15985	Lepidopteran Resistant, including, but not limited to, cotton bollworm, pink bollworm, tobacco budworm; from the hybrid cotton variety DP50B (a cross between DP50 and transgenic cotton line MON 531), expresses both Cry1Ac and Cry2Ab	Environment (import basis), food and feed. Not grown in Canada.
Cotton Seed / Gossypium hirsutum L.	Herbicide Tolerance	Bayer CropScience (Aventis CropScience (AgrEvo Canada))	LLCotton25	Glufosinate ammonium herbicide tolerant; *bar* (phosphinothricin N-acetyltransferase (PAT)) from *Streptomyces hygroscopicus*	Environment (import basis), food and feed. Not grown in Canada.
Cotton Seed / Gossypium hirsutum L.	Pest Resistance	DOW AgroSciences LLC	281-24-236	Insect-resistant cotton produced by inserting the cry1F gene from *Bacillus thuringiensis* var. *aizawai*. The PAT encoding gene from *Streptomyces viridochromogenes* was introduced as a selectable marker.	Food and Feed
Cotton Seed / Gossypium hirsutum L.	Pest Resistance	DOW AgroSciences LLC	3006-210-23	Insect-resistant cotton produced by inserting the *cry1Ac* gene from *Bacillus thuringiensis* subsp. *kurstaki*. The PAT encoding gene from *Streptomyces viridochromogenes* was introduced as a selectable marker.	Food and Feed
Cotton Seed / Gossypium hirsutum L.	Herbicide Tolerance	Monsanto Company	MON88913	Glyphosate herbicide tolerant cotton produced by inserting two genes encoding the enzyme 5-enolypyruvylshikimate-3-phosphate synthase (EPSPS) from the CP4 strain of *Agrobacterium tumefaciens*.	Food and Feed
Flax / Linum usitatissimum L.	Herbicide Tolerance	University of Saskatchewan	FP967	Sulfonylurea herbicide tolerance, specifically triasulfuron and metsulfuron-methyl; *als* from *A. thaliana* and *neo* from *Echerichia coli*	Environment, food and feed. Deregistered in 2001.

Lentil / Lens culinaris	Herbicide Tolerance	BASF	RH44	Imidazolinone herbicide tolerance, specifically imazethapyr; chemical mutagenesis of the acetohydroxyacid synthase (AHAS) gene	Environment, food and feed.
Papaya / Carica papaya	Virus Resistance	Cornell University	55-1/63-1	Resistant to Papaya ringspot virus (PRSV); virus-derived sequences that encode the PRSV coat protein (CP)	Food
Potato / Solanum tuberosum L.	Insect Resistance	Monsanto Canada	BT06, BT10, BT12, BT16, BT17, BT18, BT23	Colorado Potato Beetle Resistant; *cry3A* from Bacillus thuringiensis subspecies tenebrionis (Btt)	Environment, food and feed.
Potato / Solanum tuberosum L.	Insect Resistance	Monsanto Canada	ATBT04-6, ATBT04-27, ATBT04-30, ATBT04-31, ATBT04-36, SPBT02-5, SPBT02-7	Colorado Potato Beetle Resistant; *cry3A* from Bacillus thuringiensis subspecies tenebrionis (Btt)	Environment, food and feed.
Potato / Solanum tuberosum L.	Insect Resistance, Virus Resistance	Monsanto Canada	RBMT15-101, SEMT15-02, SEMT15-15	Colorado Potato Beetle Resistant and Potato Virus Y (PVY) Resistant; *cry3A* gene from *Bacillus thuringiensis* subsp. *Tenebrionis* and coat protein (CP) gene from PVY-O	Environment, food and feed.
Potato / Solanum tuberosum L.	Insect Resistance, Virus Resistance	Monsanto Canada	RBMT21-350, RBMT21-129, RBMT22-082	Colorado Potato Beetle Resistant and Potato Leafroll Virus (PLRV) Resistant; *cry3A* gene from *Bacillus thuringiensis* subsp. *Tenebrionis* and ORF-1 and ORF-2 regions from PLRV for resistance to PLRV infection	Environment, food and feed.
Rice / Oryza sativa	Herbicide Tolerance	BASF	CL121, CL141, CFX51	Imidazolinone herbicide tolerance; combination of accelerated mutagenesis and traditional cross-breeding	Food and feed. Can be imported. Not grown in Canada.
Rice / Oryza sativa	Herbicide Tolerance	BASF	PWC16	Imidazolinone herbicide tolerance, specifically imazethapyr; chemically induced seed mutagenesis and whole plant selection procedures, resulting in a mutation in the AHAS gene	Food and feed. Can be imported. Not grown in Canada.
Soybean / Glycine max L.	Herbicide Tolerance	Monsanto Canada	GTS 40-3-2	Glyphosate tolerant; 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) from strain CP4 of *Agrobacterium tumefaciens*	Environment, food and feed.
Soybean / Glycine max L.	Herbicide Tolerance	Bayer CropScience (Aventis CropScience)	A2704-12, A5547-127, A2704-21	Glufosinate ammonium herbicide tolerant; *pat* from *Streptomyces viridochromogenes*	Environment (A2704-12 only), food (both) and feed (both).

Soybean / Glycine max L.	Modified fatty acid content	Dupont Canada	G94-1, G94-19, G168	High oleic acid content; a second copy of fatty acid desaturase gene (*fad2*) from *G. max*	Environment, food and feed.
Soybean / Glycine max L.	Modified fatty acid content	Agriculture and Agri-Food Canada	OT96-15	Low linolenic acid content; traditional plant breeding methods using the variety Maple Glen and PI361088B	Food
Squash / Cucurbita pepo	Virus Resistance	Seminis Vegetable Inc.	CZW-3	Resistant to cucumber mosaic virus (CMV), watermelon mosaic virus (WMV) 2, zucchini yellow mosaic virus (ZYMV); virus-derived sequences that encode the coat proteins (CPs) from each of these viruses	Food. Not grown in Canada.
Squash / Cucurbita pepo	Virus Resistance	Seminis Vegetable Inc.	ZW20	Resistant to watermelon mosaic virus (WMV) 2, zucchini yellow mosaic virus (ZYMV); virus-derived sequences that encode the coat proteins (CPs) from each of these viruses	Food. Not grown in Canada.
Sugar Beet / Beta vulgaris	Herbicide Tolerance	Bayer CropScience (Aventis CropScience (AgrEvo Canada))	T120-7	Glufosinate ammonium herbicide tolerant; *pat* from *Streptomyces viridochromogenes*	Environment, food and feed.
Sugar Beet / Beta vulgaris	Herbicide Tolerance	Monsanto Company	H7-1	Glyphosate herbicide tolerant sugar beet produced by inserting a gene encoding the enzyme 5-enolypyruvylshikimate-3-phosphate synthase (EPSPS) from the CP4 strain of *Agrobacterium tumefaciens*.	Food
Sunflower / Helianthus annus	Herbicide Tolerance	BASF	X81359	Imidazolinone herbicide tolerance; traditional plant breeding techniques	Food (oil use only), feed (meal and oil only) and Environment (imports) (meal and oil only)
Tomato / Lycopersicon esculentum	Delayed Ripening	Monsanto (Calgene Inc.)	FLAVR SAVR	Delayed softening; insertion of an additional copy of the PG encoding gene in the “antisense” orientation	Food. Not grown in Canada and not fed to animals.
Tomato / Lycopersicon esculentum	Delayed Ripening	DNA Plant Technology Corporation	1345-4	Increased shelf life (delayed ripening); truncated ACC synthase gene	Food. Not grown in Canada and not fed to animals.

Tomato / Lycopersicon esculentum	Delayed Ripening	Advanta Seeds (Zeneca Seeds)	(B, Da, F) 1401F, H382F, 11013F, 7913F	Delayed softening; truncated version of the PG encoding gene in either the sense (lines Da and F) or the "antisense" (line B) orientation	Food. Not grown in Canada and not fed to animals.
Tomato / Lycopersicon esculentum	Pest Resistance	Monsanto	5345	Lepidopteran resistant including, but not limited to, cotton bollworm, pink bollworm, tobacco budworm; *cry1Ac* from *Bacillus thuringiensis* subsp. *kurstaki* strain HD73	Food. Not grown in Canada and not fed to animals.
Wheat / Triticum aestivum	Herbicide Tolerance	Cyanamid Crop Protection	SWP965001	Imidazolinone herbicide tolerant, specifically Cyanamid AC299 263; chemically induced seed mutagenesis	Environment, food and feed.
Wheat / Triticum aestivum	Herbicide Tolerance	BASF	AP602CL	Imidazolinone herbicide tolerant, specifically Cyanamid AC299 263; chemically induced seed mutagenesis of wheat variety Gunner	Environment, food and feed.
Wheat / Triticum aestivum	Herbicide Tolerance	BASF	AP205CL	Imidazolinone herbicide tolerant, specifically Cyanamid AC299 263; chemically induced seed mutagenesis of wheat variety Gunner	Environment, food and feed.
Wheat / Triticum aestivum	Herbicide Tolerance	BASF	Teal 11A	Imidazolinone herbicide tolerant; chemically induced seed mutagenesis	Environment, food and feed.

Source: Canadian Food Inspection Agency, AgBios (Updated August, 2006)

Coexistence Between Biotech and Non-Biotech Crops

In Canada, the coexistence between biotechnology and non-biotechnology crops is not regulated by the government, but rather the onus is on the producers. For example, if producers of organic crops wish to avoid GM events in their production systems the onus for implementing measures to facilitate this falls on them. In return, those producers are able to charge a premium price for their product, for incurring costs associated with meeting the requirements of their customers and certification bodies.

Biotech stewardship conditions applies to biotech crops in Canada, with some companies providing biotech crop farmers with coexistence type recommendations for minimizing the chances of adventitious presence of biotech crop material being found in non-biotech crops of the same species. In addition, producers of biotech crops are provided with weed management practice guides. These changes in management practices may help to improve the coexistence between biotech and non-biotech crops, without the need to introduce government regulations. For example, Croplife Canada has developed the Stewardshipfirst™ initiatives in order to manage the health, safety and environmental sustainability of the industry's products throughout their life cycle. Stewardshipfirst™ includes Best Management Practices Guide for growers of GM crops.

Despite the fact that the government does not regulate the coexistence between biotech and non-biotech crops, the presence and increasing trend toward biotech crops has not hindered the organic industry. The growth or lack-there-of in the organic industry is based on demand by consumers, rather than the presence or absence of biotech crops. There have been disputes between the biotech community and the organic community due to adventitious presence of biotech crops (for example canola) in organic crops, but the lack of complete information indicting the actual levels of the biotech crops in organic crops, the frequency of testing of organic crops, location of crops relative to biotech

crops, the origin of seed, measures taken to minimize adventitious presence occurring, means that it is not possible to fully assess whether there have been or may be coexistence problems between organic and biotech crops in Canada.

Labeling of Genetically Modified Products

In 2004, the Standards Council of Canada adopted the *Standard for Voluntary Labeling and Advertising of Foods that Are and Are Not Products of Genetic Engineering*, as a National Standard of Canada. The development of the voluntary standards was carried out by multi-stakeholder committee, facilitated by the Canadian General Standards Board (CGSB), at the request of the Canadian Council of Grocery Distributors, and began in November 1999. The committee was made up of 53 voting members and 75 non-voting members from producers, manufacturers, distributors, consumers, general interest groups and six federal government departments, including Agriculture and Agri-Food, Health Canada and the CFIA.

Health Canada and the CFIA are responsible for all federal food labeling policies under the *Food and Drugs Act*. Health Canada is responsible for setting food labeling policies with regards to health and safety matters, while the CFIA is responsible for development of non-health and safety food labeling regulations and policies. It is the CFIA's responsibility to protect consumers from misrepresentation and fraud with respect to food labeling, packaging and advertising, and for prescribing basic food labeling and advertising requirements applicable to all foods.

The *Standard for Voluntary Labeling and Advertising of Foods that Are and Are Not Products of Genetic Engineering*, was developed to provide customers with consistent information for making informed food choices while providing labeling and advertising guidance for food companies, manufacturers and importers. The definition of genetically engineered food provided by the Standard are those foods obtained through the use of specific techniques that allow the moving of genes from one species to another. The regulations outlined in the Standard are:

- The labeling of food and advertising claims pertaining to the use or non-use of genetic engineering are permissible as long as the claims are truthful, not misleading, not deceptive, not likely to create an erroneous impression of a food's character, value, composition, merit or safety, and in compliance with all other regulatory requirements set out in the *Food and Drugs Act*, the *Food and Drugs Regulations*, the *Consumer Packaging and Labeling Act* and *Consumer Packaging and Labeling Regulations*, *the Competition Act* and any other relevant legislation, as well as the *Guide to Food Labeling and Advertising*.
- The Standard does not imply the existence of health or safety concerns for products within its scope.
- When a labeling claim is made, the level of accidental co-mingling of genetically engineered and non-genetically engineered food is less than 5 percent.
- The Standard applies to the voluntary labeling and advertising of food in order to distinguish whether or not such foods are products of genetic engineering or contain or do not contain ingredients that are products of genetic engineering, irrespective of whether the food or ingredient contains DNA or protein.
- The standard defines terms, and sets out criteria for claims and for their evaluation and verification.
- The standard applies to food sold to consumers in Canada, regardless of whether it is produced domestically or imported.
- The standard applies to the labeling and advertising of food sold prepackaged or in bulk, as well as to food prepared at the point of sale.
- The standard does not preclude, override, or in any way change legally required information, claims or labeling, or any other applicable legal requirements.
- The standard does not apply to processing aids, enzymes used in small quantities, substrates for microorganisms, veterinary biologics and animal feeds.

The fight in Canada for mandatory labeling of genetically engineered food continues despite the creation and implementation of the Standard. Currently there is a Private Member's bill in the House of Commons calling on the government to implement mandatory labeling on products created through genetic modification (genetic engineering). The bill was presented before Parliament in December

2004, but has not been debated or voted on since. Some Members of Parliament strongly endorse the need for mandatory labeling and will support this bill, but most MP's will not vote in favor of implementing mandatory labeling and therefore will most likely defeat this bill.

The Cartagena Protocol on Biosafety

In 2001, Canada signed onto the Cartagena Protocal, but has yet to ratify it. There is tremendous opposition from many farm groups, like the Canadian Canola Council, the Grain Growers of Canada, Agricore United and many others, to the ratification of the Protocol. There are also those groups like the National Farmers Union and Greenpeace, who are pushing the government to ratify it. To determine the best course of action in regards to the Protocol, the Government of Canada has been consulting with stakeholders. The consultations have resulted in three options on how the government should proceed being put forward:

a. Proceed to immediate ratification of the Protocol with the intent to participate as a Party in the first meeting of the Parties;
b. Keep the decision on ratification under active review while continuing to participate in Protocol processes as a non-Party and acting voluntarily in a manner that is consistent with the objective of the Protocol;
c. Decide not to ratify the Protocol.

The position the Government of Canada has taken follows along the line of option b. The three Ministers responsible for deciding on whether or not to ratify the Protocol are split in their positions. The Minister of Agriculture and Agri-Food and the Minister of International Trade have both indicated that they are opposed to ratification of the Protocol, but the Minister of the Environment has indicated that he is leaning towards ratification. With two major ministers opposing ratification, the likelihood of ratification is very small.

In the event that the government does choose to ratify the Protocol, Environment Canada has published a copy of the regulation pursuant to the *Canadian Environmental Protection Act, 1999* (CEPA, 1999) that the department proposes to put in place to implement the Protocol if the government chooses to ratify it. A copy of these regulations can be found at: http://www.ec.gc.ca/substances/nsb/eng/reg_e.htm.

The CFIA has also published its proposed regulation to implement the Cartagena Protocol on Biosafety, if the government chooses to ratify the agreement, pursuant to the *Canada Agricultural Products Act*. The regulations would specifically cover agricultural products, including plants, plant products, fertilizers, feeds and veterinary biologics. The consultation document on the CFIA proposed regulations can be found at: http://www.inspection.gc.ca/english/sci/biotech/consult/consulte.shtml.

Canada and Canadian industries rely heavily on imports of U.S. crops to meet their requirements. Therefore, the ratification of the Cartagena Protocol could become a barrier to trade with the United States.

Intellectual Property Rights

The *Patent Act* and the *Plant Breeders' Rights Act* both afford breeders or owners of new varieties the ability to collect technology fees or royalties on their products. The *Patent Act* grants patents that cover the gene in the plant or the process used to incorporate the gene, but does not provide a patent on the plant itself. The protection of the plant would be covered by the *Plant Breeders' Rights* (PBR) *Act*. The *Patent Act* enables breeders to sell their product commercially to producers. The cost of the patented product will most likely include technology fees. This enables the breeders to recover the financial investment they have made in developing their product.

The *Plant Breeders' Rights* (PBR) *Act* grants plant breeders of new varieties the exclusive rights to produce and sell propagating material of the variety in Canada. The PBR Act outlines that the holder of the plant breeders' rights is able to collect royalties on the product. The PBR Act became law in 1990 and adhered to the terms of the 1978 Union for the Protection of New Varieties of Plants (UPOV) Convention. In 1992, Canada was a signatory to 1991 UPOV Convention. In order to bring the PBR Act

into compliance with the new convention, Canada must make amendments PBR Act. Consultations involving the Plant Breeders' Rights Office, the Canadian seed industry, representatives from the horticulture and agriculture industries and the Minister's Plant Breeders' Rights Advisory Committee have resulted in the development of amendments which would bring the PBR Act into conformity with 1991 UPOV Convention.

SECTION IV. MARKETING

Overall market acceptance of biotechnology crops and products is strong in Canada. Many producers have taken advantage of the benefits of growing biotech crops, including reduced herbicide use, and a reduction in losses due to insect resistant and disease resistant traits. Despite the opposition in some countries to importation of genetically modified (GM) crops, Canadian producers have been able to secure markets for their GM crops. For example, Japan is one of the largest importers of Canadian canola, of which a majority is GM. The Canadian Canola Council is a very proactive industry group, developing and securing markets for Canadian canola, as well as ensuring Canadian consumers are aware of the benefits of consuming canola. With the development of GM canola that is high in oleic acids and low linonlenic acids, the Canola Council has been promoting the health benefits of consuming this particular variety of GM canola. Acreage seeded to GM canola continues to increase each year, which is a testament to the success and acceptance of GM canola in Canada and in international markets.

Canadian flax producers have not met the same success in regards to the marketing of GM flax. The issue facing Canadian flax producers was not opposition to GM flax at home, but in exports of flax to Canada's largest market, the European Union. In the late 1990's Triffid flax seed, an herbicide tolerant variety, was registered and approved by the CFIA and Health Canada for commercial production and consumption. But EU consumers indicated that they would not purchase GM flax. Canadian flax producers were concerned that they would be unable to keep GM and non-GM flax segregated and rather than risking their largest market, Canadian flax producers pushed to have Triffid deregistered and pulled from the market. The concern over the loss of the EU market continues to plague the Canadian flax industry and may interfere with several companies' plans to introduce new GM varieties of flax into the Canadian market. But the health benefits of the GM flax created to be high in omega-3 fatty acids may supersede concerns of the Canadian flax producers, as more and more consumers in Canada are demanding additional sources of omega-3 fatty acids.

The largest issue regarding market acceptance of a biotech crop was the recent uproar regarding the regulatory approval of Round-up Ready (RR) wheat by Monsanto. The issue of RR wheat in Canada became very divisive. Some producers believed in the benefits of growing RR wheat and supported its regulatory approval, while other producers feared the approval and commercialization of RR wheat would cost Canadian wheat farmers their international markets. This fear was fueled by the refusal of major customers to accept any RR wheat. As the only marketing agency for Western Canadian wheat in the international marketplace, the Canadian Wheat Board (CWB) was vehemently opposed to the regulatory approval and commercialization of RR wheat.

The CWB is apart of the Canada Grain Industry Working Group (CGIWG), and was involved in the drafting of conditions they deemed necessary in order to permit the commercial introduction of GM wheat in Canada. The position of the CWB is that the commercial release of GM wheat (including RR wheat) should not occur until the conditions developed by the CGIWG have been met. The conditions developed by the CWB and the working group for the commercial release of GM wheat are: market acceptance, segregation systems, agronomic information and cost-benefit analysis. The group defined market acceptance as:

> Identified markets for the GM product, as well as the ability to meet the needs of key non-GM markets so that farmers are not negatively impacted by lost markets.

The first condition for market acceptance was that GM products had to receive regulatory feed, food and environmental approval, whichever is applicable, in the country of destination. In markets where regulatory approval has not been received, an achievable tolerance level for unapproved events must exist.

The second condition under market acceptance was that there were identified markets for GM wheat.

The third condition for market acceptance was the ability to meet non-GM market requirements, including the establishment of achievable tolerance levels for the presence of GM material in non-GM shipments. The tolerance levels must be physically possible and economically feasible to meet. In addition, tolerance levels must be established for each step of the supply chain.

The final condition for market acceptance was market harm. Market harm exists when major customers indicate that they will not purchase GM wheat and require certification stating shipments do not contain GM wheat. In addition, market harm exists when set tolerance levels are not achievable or the cost to achieve the set tolerance levels results in an uncompetitive product. The extent of market harm must be established and evaluated against any possible market, agronomic or other benefit expected.

A segregation system was the second condition required by the CGIWG. The CGIWP wanted the establishment of a segregation system to prevent the co-mingling of GM and non-GM wheat prior to the release of GM wheat. The segregation system envisioned by the CGIWG would be closed-loop.

The third condition of the CGIWG was agronomic information. The working group wanted a clear understanding of the impact commercial release of GM wheat would have on management practices and profitability with respect to each type of farming operation across a multi-year rotation. This condition also called for additional research to be reviewed by a panel of agronomists.

The final condition of cost-benefit analysis would include an analysis of the market and agronomic benefits, and the market and agronomic risks and costs for all production and marketing systems and for technology adaptors and non-adaptors. This would include investigating yield impacts, cost of production, interaction between GM wheat and other crops in farmers' rotations, market benefit, lost market revenue, segregation costs, real option value, expected net return, irreversible market costs and irreversible environmental costs.

In addition to wanting these conditions met prior to the release of any GM wheat, was the push by several farm groups including the CWB, to have the regulatory process amended to include a cost-benefit analysis before regulatory approval should be granted. Despite the pressure by the CWB and other groups to amend the regulatory process, the Government of Canada has resisted making changes to the regulatory system to include market acceptance as a mandatory condition for the approval of a PNT. The Government continues to base Canadian regulations on science.

The push by CWB to implement its conditions for the commercial release of GM wheat and for changes to the regulatory approval process will make Canada a less attractive place for the commercial introduction of GM wheat and possibly other GM crops.

Additional Issues

Canada's smallest province, Prince Edward Island (PEI) is currently holding hearings to determine if the provincial government should ban the production of GM crops in the province. The organic producers in PEI support the ban, but there are many producers who are opposed. The Standing Committee on Agriculture, Forestry and Environment is hearing arguments from industry and farm groups from across the continent and will make a final recommendation to the government based upon what they have heard. Initially the momentum towards the ban was strong, but the momentum is losing steam due to the strong opposition put forth by some major farm and industry groups.

SECTION V. REFERENCE MATERIAL

AgBios
www.agbios.com

AGCare
www.agcare.org

Agricore United
www.agricoreunited.com

Agriculture and Agri-Food Canada
www.agr.gc.ca

AgWest Bio Inc.
www.agwest.sk.ca

BIOTECanada
www.biotech.ca

Canadian Biotechnology Advisory Committee
www.cbac-cccb.ca

Canadian Food Inspection Agency
www.inspection.gc.ca/english/toc/bioteche.shtml

Canadian General Standards Board
www.pwgsc.gc.ca/cgsb/home/index-e.html

Canadian Wheat Board
www.cwb.ca

Canola Council of Canada
www.canola-council.org

Council For Biotechnology Information
www.whybiotech.ca

Croplife Canada
www.croplife.ca/english/index.cfm

Dietetics @ Work
www.dieteticsatwork.com/index.asp

Environment Canada
www.ec.gc.ca

Genome Canada
www.genomecanada.ca

Grain Growers of Canada
www.ggc-pgc.ca

Health Canada
www.hc-sc.gc.ca

Ontario Soybean Growers
www.soybean.on.ca

Plant Biosafety Office
www.inspection.gc.ca/english/plaveg/bio/pbobbve.shtml

Plant Breeders' Rights Act
http://laws.justice.gc.ca./en/P-14.6/fulltoc.html

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www.rsc.ca

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